MINUTES OF THE IDAHO STATE BOARD OF PHARMACY August 12, 2010

State Capital - Boise, Idaho

This meeting of the Board is held to conduct regular Board business.

Chairman Holly Henggeler, Pharm D, called the meeting to order at 8:06 a.m. In attendance were Board members Berk Fraser, R.Ph.; Nicole Chopski, Pharm D; and Rich de Blaquiere, Pharm D; Mark Johnston, R.Ph, executive director; Jenifer Marcus, DAG; Fred Collings, Chief Investigator, Wendy Hatten and Ellen Mitchell. Ms. Gurnsey was unable to attend.

The minutes from the last meeting were reviewed; motions were clarified and they were correct. Jan Atkinson noted a typo correction on the last page regarding Fiscal year ending data, should state not 'compiled' instead of 'complied'. Dr. Chopski motions to approve the minutes of the July 9, 2010 meeting, Mr. Fraser seconded, motion carried unanimously.

In the matter of Mr. Kelly Carpentier's request for reinstatement, an incomplete application for reinstatement was initially received on June 24, 2010. The Board sent Mr. Carpentier a response letter with a correct application and procedures to follow with a deadline of August 4, 2010 in order to be on this agenda. Ms. Marcus stated that Staff recommendation is in opposition to reinstatement. Mr. Johnston asked Board and Ms. Mitchell if they should be waiting for Mr. Carpentier to appear for this meeting. Ms Mitchell stated that Mr. Carpentier delivered the correct application, an indication that he was aware of this hearing, and thus the assumption was that he chose not to be in attendance. Ms. Atkinson noted that proof of continuing education was provided through 2008 only and not for 2009 or 2010. Mr. Fraser motions to deny the application, Dr. de Blaquiere seconded, motion carried unanimously.

Mr. Johnston presents the Board of Medicine's response letter regarding delivery of legend drugs by practitioners. Mr. Johnston has been invited to their meeting in September to present in person. Dr. Chopski inquires about a note in the letter recommending/suggesting that the board provides awareness of current regulations during renewal. Mr. Johnston's response is that there are no current regulations, but there are 2 statutes of relevance: labeling requirements and Controlled Substance inventory and keeping requirements. Dr. Henggeler inquired as to steps that are going to be taken to move forward with this issue. Mr. Johnston expressed his desire to work with all parties involved, including the many Boards who license prescribers. Mr. Collings sent a letter to all wholesalers and manufacturers, requesting data on Rx items being wholesaled to prescribers, in an attempt to identify those delivering more than samples. Currently, the Board has the authority investigate controlled substance issues, but not inspect prescribers. A change to rule #469 is the extent of what is proposed on the topic for 2011.

Kent Alexander asks the Board for approval to compound Domperidone, as Dicks Pharmacy is compounding with Domperidone, screening for use in lactating mothers. Ms Atkinson's letter indicates that Domperidone is not an FDA approved medication, as evidence by several FDA warning letters, and rule #151 requires only FDA products to be stocked in an Idaho licensed pharmacy. The Board disagrees that rule #151 requires only FDA drugs to be stocked. The Board supports its 2002 decision, not disallowing the compounding of Domperidone, as there is no rule that prohibits such activity. The Board does not have enforcement rights for FDA law and warns Mr.

Alexander that said compounding is not legal federally. The Board's current draft compounding rules would prohibit said compounding, as Domperidone also does not have a USP/NF monograph. Mr. Johnston is directed to form a committee to review the proposed compounding rules.

Mr. Johnston reported that all Legislative Idea Forms were approved by DFM yesterday.

Mr. Johnston presented draft language changing three statutes in order for Idaho to allow the electronic prescribing of controlled substances, in conjunction with recent federal action. The Board approved the draft, unchanged.

Mr. Johnston presented a statute change that would allow limited prescriptive authority for pharmacists. Additional changes would allow pharmacists to prescribe CV medications. Dr. Chopski pointed out that the proposal is too broad and includes items such as lomotil, not just what is allowed in current rule 451. The Board approved draft changes to the definition of the practice of pharmacy, but directed Mr. Johnston to draft language that only allows for pharmacist prescribing of CV, liquid, codeine containing products.

Mr. Johnston presents statute changes that would move counseling requirements to a location that would clarify that the statute regulates retail pharmacies. Additionally, the pharmacist offer to counsel is proposed on all medications only, not new prescriptions or refills. The requirement of a prospective drug review would remain for all pharmacists. The Board approves the draft, unchanged.

Mr. Johnston presents changes to schedule II, in conjunction with federal changes. The Board approves the draft, unchanged.

Mr. Johnston presents changes to the definition of drug outlet and the list of outlets registered, however, he would like to rescind the proposal to list mail order pharmacies, as such outlets are licensed, not registered. Additionally, conflicting language that does not allow for the registration of drug outlet employees is proposed to be struck, and a site reference section is proposed to be clarified. The Board approves the draft language with one additional site reference clarification.

Mr. Johnston presents 9 rule changes necessary for Idaho to allow the electronic prescribing of controlled substances in conjunction with the recent DEA changes. The Board had previously voted to include draft language from the rule rewrite project, when possible. Thus, these changes include more substantive changes than necessary for electronic prescribing. The Board directs Mr. Johnston to only require a full patient name on prescription drug orders for controlled substances, to include the strength on the prescription label, and to except compounded preparations from the product description requirement on the prescription label. The Board directs Mr. Johnston to strike confusing prescription transfer language concerning pharmacies using common electronic files. A discussion ensued concerning the use of the word "administration" Vs "dispensing" in the new definition of emergency; ultimately, the federal definition was utilized. The Board approves of the draft language for these 9 rules with said corrections.

Mr. Johnston presented the striking of rule #358, as it is in conflict with the Idaho Wholesale Drug Distribution Act. Mr. Johnston reported that all registered veterinarian drug outlets were informed of this proposed action in writing. The Board approved of the draft language, unchanged.

Mr. Johnston presented draft language that requires prescribers delivering controlled substances, except samples, to report such dispensing to the Prescription Monitoring

Program's Controlled Substance Database. The Board approved of the draft language, unchanged.

Mike Dickens, ISHP President, is absent, so Mr. Johnston presented the work of the Institutional Rules Review Committee. Mr. Johnston thanked the Rules Review Committee for their dedication. The current rule book has 15 pages of institutional rules and now 15 pages of institutional rules are proposed, much more comprehensive and up to date. The committee will return at the October meeting, expecting to present a final version.

Lynette Berggren, Board consultant, presented a change document, listing all changes to the proposed rules since the last Board meeting. Mr. Johnston pointed out that a requirement to be FDA approved is missing from the proposed compounding rules, although the alternative USP/NF listing remains. The Board decided to not consider language that would allow for reduced patient profile information for transitional patients, to table the topic of pharmacist verification of tech stocked ADS machines after today's hospital tour, to require student pharmacists to wear name badges, to better define the term authorized personnel, to strike a technical equipment requirement, and to require the full name of the prescriber on prescription drug orders.

In the Jeff Middleton, mitigation hearing, David Leroy presented as Mr. Middleton's attorney. Mr. Middleton has stipulated to facts describing his diversion, but would like to retain his pharmacist license, voluntarily surrendering his controlled substance registration, so that he may obtain a clinical pharmacist position. Ms. Magnelli presented the Board's position, supported by Southworth Associates, the company that manages the Board's PRN program: Mr. Middleton should enroll in the PRN program, attend a 72 hour in-patient evaluation program and follow the prescribed treatment program developed at said in-patient evaluation. As Mr. Middleton was offered the chance to enroll voluntarily and chose not to, the Board staff's position also involves a one year suspension. Mr. Leroy and Mr. Middleton spoke to the successful out-patient treatment that Mr. Middleton has been attending and the expense of in-patient treatment. Dr. de Blaquiere motioned to accept Ms. Magnelli's recommendation. Dr. Fraser seconded, motion carried unanimously.

Ms. Magnelli presented Derek Molyneux's Stipulation and consent order. Mr. Johnston requested a PRN policy change, such as used in this stipulation. Previously, the policy allowed for a volunteer to avoid suspension, but that a licensee or registrant whose diversion was reported to the Board via being arrested, employment termination, etc. should be suspended for one year. Mr. Johnston stipulated with Mr. Molyneux for a 6 month suspension, if he joined the PRN program, after being reported to the Board, so that he may obtain treatment in a timely manner, not awaiting the same likely discipline (one year suspension) at a future hearing date. The Board agreed to said policy change. Dr. Chopski motioned to accept the stipulation. Dr. Fraser seconded. After further discussion, the motion carried unanimously.

Kim Anton's request for modification of her order was heard via conference call. Ms. Anton requested a modification eliminating her restriction of acting as a PIC. Mr. Collings reported that Ms Anton is compliant with her Board ordered drug screenings. Dr. Fraser motioned to modify the order and approve her request, including removing the restriction of acting as a preceptor. Dr. Chopski seconded, motion carried unanimously.

Mr. Johnston presented the Board travel calendar. Dr. Chopski graciously volunteered to attend the ISU White Coats Ceremony, presenting for the Board.

Glenn Luke presented the Board's fiscal year ending financial report.

Dr Henggeler asked the inspectors if they had any questions. Ms. Atkinson addressed Board Rule 251.02. Do stores that use inventory companies to complete pharmacy inventory need to register the personnel as technicians? Mr. Johnson quoted the rule, allowing temporary visitors for legitimate business purposes. The Board will allow this presence without registration required.

Ms. Atkinson received a letter from a pharmacy that has a hazardous waste disposal facility in the hospital used for cancer hazardous waste/medications. The pharmacy would like to accept previously dispensed chemotherapy medication for destruction, in the name of public safety. Mr. Johnston indicated rule #156 prohibits this, explaining that the Board can't provide a waiver to a rule yet. Mr. Johnston explained the statute that passed this year allows a state or federal agency to license a business to take returns directly from the end user, but no one is currently licensed or registered as per this statute change. The Board determined that EPA, DEQ or a similar agency needs to address this issue.

Mr. Fraser motioned to adjourn, Dr. de Blaquiere seconded. Motion carried unanimously. Meeting adjourned at 2:52 pm, for the Board to tour St Luke's.

Chairman	Vice-Chairman
Member	Member
Member	Executive Director